



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,220	01/31/2002	Burkhard Schulz	DEBE IPCT SEQ/dln	1762
25666	7590	04/20/2005	EXAMINER	
THE FIRM OF HUESCHEN AND SAGE 500 COLUMBIA PLAZA 350 EAST MICHIGAN AVENUE KALAMAZOO, MI 49007			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,220	Applicant(s) SCHULZ, BURKHARD	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) 16,21,22,28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,17-20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 2/2/2005 has been entered.

2. Claims 14 and 16-29 are pending.

Claims 1-13 and 15 have been canceled.

Claims 27-29 have been newly added.

3. Newly submitted claims 28-29, directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 28-29 are drawn to nucleic acids in antisense orientation and a method comprising a nucleic acid in antisense orientation, both of which read on the claims of Group VI from the restriction mailed 3/11/2004.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 16, 21-22 and 28-29 have been withdrawn from consideration for being drawn to non-elected inventions.

4. Claims 14, 17-20, and 23-27 are examined in the present office action.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

6. Rejections and objections not set forth below are withdrawn.

Art Unit: 1638

Information Disclosure Statement

7. The Chemical Abstracts listed on form 1449 have not been considered, as they were not provided by the Applicant, with the exception of Vol. 128, 1998, 85834j. As stated in the MPEP

§ 1.98 (a) Any information disclosure statement filed under § 1.97 shall include: (1) A list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) A legible copy of:

(i) Each foreign patent;

(ii) Each publication or that portion which caused it to be listed;

In addition, each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication. (See 37 CFR 1.98).

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18, 23-24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

Art Unit: 1638

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14 and 19 have been amended to recite “and non-functional derivatives thereof”. Applicants contend that support for this phrase is found on page 6 of the instant specification. Applicants contend that the specification defines non-functional derivatives thereof as nucleic acids having one or more deletions, substitutions, insertions and/or inversions (page 3, second paragraph). The Office contends that on page 6, lines 8-9, the term “derivate” is defined as a nucleic acid or amino acid having one or more deletions, substitutions, insertions and/or inversions. The Office contends that the specification does not support or disclose “non-functional derivatives thereof”.

Claim 27 is drawn to the isolated nucleic acid of claim 14 which encodes a polypeptide of the sequence set forth in SEQ ID NO:3, but Applicants have not pointed to where in the specification support can be found for this claim.

Applicants are required to point to support for “and non-functional derivatives thereof” and “nucleic acids of claim 14 encoding SEQ ID NO:3” or to amend the claims to delete the NEW MATTER.

Written Description

9. Claims 14, 17-20, and 23-26 remain rejected and claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This

Art Unit: 1638

rejection is maintained for the reasons of record set forth in the Official action mailed 7/29/2004.

Applicant's arguments filed 2/2/2005 have been fully considered but they are not persuasive.

Applicants contend that any nucleic acid deletion, substitution, inversion, and/or insertion in SEQ ID NO:2 which results in a non-functional nucleic acid, one which does not encode a functional TWD protein, falls within the scope of the claim. Applicants contend that those skilled in the art are well-versed in manipulating nucleic acid sequences to abolish protein expression from a functional gene (page 3, middle paragraph). Applicants contend that methods for generating non-functional derivatives of SEQ ID NO:2, by introducing a T-DNA insertion are known (paragraph bridging pages 3 and 4).

The Office contends that Applicants fail to describe a representative number of polynucleotide sequences from a representative number of plants encoding SEQ ID NO:2, or encoding non-functional derivatives thereof. Furthermore, Applicant fails to describe structural features common to members of the claimed genus of polynucleotides. Disclosing a method, i.e., T-DNA insertational mutagenesis, does not fulfill the requirements for written description.

Applicants also contend that a description of three non-functional derivatives of SEQ ID NO:2 that are disclosed in the specification (page 20, Example 4) fulfill the written description for claims drawn to non-functional derivatives of SEQ ID NO:2 (page 4, 1st full paragraph).

The Office contends that Applicants claims are drawn to any non-functional derivative of SEQ ID NO:2 but Applicants have only disclosed 3 mutant alleles from Arabidopsis. A disclosure of three mutant alleles and one wild-type allele from Arabidopsis does not fulfill the written description requirement for claims drawn to all non functional alleles of SEQ ID NO:2 from all plants.

Enablement

10. Claims 14, 17-20, and 23-26 remain rejected and claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/29/2004. Applicant's arguments filed 2/2/2005 have been fully considered but they are not persuasive.

Applicants contend that the specification provides an enabling disclosure for the isolation of the nucleic acid sequence set forth in SEQ ID NO:2 and demonstration of several uses of the nucleic acid to satisfy the enablement requirement (paragraph bridging pages 4 and 5). Applicants contend that they have demonstrated that non-functional derivatives of SEQ ID NO:2, harbored by transgenic plants exhibit an effect on plant architecture (page 5, 1st full paragraph).

The Office contends that Applicants have not disclosed how one would use a plant transformed with a nucleic acid encoding SEQ ID NO:2. SEQ ID NO:2 is the wild-type nucleic acid encoding a wild-type, functional protein. Applicants have not disclosed a plant exhibiting any new trait or characteristic when the nucleic acid of SEQ ID NO:2 is transformed into a plant. In regards to non-functional derivatives of SEQ ID NO:2, Applicants have only shown that when the endogenous nucleic acid of SEQ ID NO:2 in Arabidopsis is mutant, the plant exhibits an altered characteristic. But, Applicants claims are drawn to transforming a plant with an isolated nucleic acid encoding SEQ ID NO:2 or a non-functional derivative thereof. The Office contends

Art Unit: 1638

that transforming a plant with the nucleic acid of SEQ ID NO:2 or non-functional derivatives thereof will not produce a plant with any altered characteristic, since the wild-type allele of SEQ ID NO:2 is still present in the Arabidopsis plant.

Applicants contend that techniques are disclosed in the specification or in the prior art that teach how to disrupt normal gene function so as to generate the disclosed phenotypic changes (paragraph bridging pages 5 and 6 and page 6, 1st full paragraph). Applicants contend that the specification and the prior art disclose how one skilled in the art would use non-functional derivatives of SEQ ID NO:2. Applicants disclose that plants comprising a non-functional derivative of SEQ ID NO:2 exhibit a disoriented growth which is a desired quality. Applicants contend that methods for producing plants with a non-functional SEQ ID NO:2 can be generated by homologous recombination as taught by Hodges et al (June, 1996, U.S. patent 5,527,695) (paragraph bridging pages 6 and 7; page 7, 1st and 2nd full paragraphs).

The Office contends that undue trial and error experimentation would be required by one of skill in the art to practice the claimed invention. The Office contends that identifying non-functional derivatives of SEQ ID NO:2 using the claimed method, i.e., homologous recombination, requires undue experimentation. The Office contends that homologous recombination in plants is not an efficient method of gene disruption. Using homologous recombination in plants is not considered routine experimentation. For each potential non-functional nucleic acid sequence derivatives of SEQ ID NO:2 that has to be tested, tens of thousands of transgenic plants have to be screened and tested to determine if the observed phenotype is the result of a homologous recombination event. Therefore, Applicants claimed sequences and method is not enabled.

102(b)

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Peattie et al (June, 1998, U.S. Patent Number 5,763,590).

The claims are drawn to an isolated nucleic acid sequence that is a non-functional fragment of SEQ ID NO:2 and a vector comprising said nucleic acid sequence and further comprising one or more regulatory elements.

The Office interprets a non-functional derivative of SEQ ID NO:2 to read on one base pair because Applicants define a non-functional derivative of SEQ ID NO:2 as having one or more deletions, substitutions, insertions and/or inversions (see Applicants response filed 2/2/2005, page 3, middle paragraph).

Peattie et al disclose a nucleic acid sequence that comprises at least one base pair. The sequence of Peattie et al is included in a vector and comprises regulatory elements (columns 12-14, Examples 4, and 6) and as such, Peattie et al anticipate the claimed invention.

Applicant's arguments filed 2/2/2005 have been fully considered but they are not persuasive. Applicants contend that the instant amendment, defining the claim scope to the sequence set forth in SEQ ID NO:2 and non-functional derivatives thereof distinguishes over the cited prior art. This subject matter is not anticipated by Peattie et al (page 8, 2nd full paragraph).

The Office contends that the amended claims read on one base pair as discussed above, and as such, Peattie et al continue to anticipate the claimed invention.

12. Claims 14, 17-20, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Holt (February, 1999, U.S. Patent Number 5,866,791).

The claims are drawn to a nucleic acid sequence that is a non-functional derivative of SEQ ID NO:2, and a vector comprising said nucleic acid sequence and further comprising one or more regulatory elements, a method for the production of plants comprising said nucleic acid sequence operably linked to one or more regulatory elements, and a transgenic plant and seeds comprising said nucleic acid sequence.

The Office interprets a non-functional derivative of SEQ ID NO:2 to read on one base pair because Applicants define a non-functional fragment of SEQ ID NO:2 as having one or more deletions, substitutions, insertions and/or inversions (see Applicants response filed 2/2/2005, page 3, middle paragraph).

Holt discloses a DNA sequence that comprises a base pair of Applicant's SEQ ID NO:2 (Claim 1 of Holt). Holt discloses a recombinant DNA comprising said sequence operably linked to transcription initiation sequence which the Office interprets as a regulatory element (Claim 2 of Holt). It would be inherent that the sequence of Holt with accompanying transcription initiation sequence would be included in a vector. Holt teaches a plant and seed transformed with said sequence and accompanying transcription initiation sequence and the plant of Holt inherently teach a method for the production of plants comprising said sequence and accompanying transcription initiation sequence, and as such, Holt anticipates the claimed invention (Claims 5, 7, 8 of Holt).

Art Unit: 1638

Applicant's arguments filed 2/2/2005 have been fully considered but they are not persuasive. Applicants submit that the instant amendment, defining the claim scope to SEQ ID NO:2 and non-functional derivatives thereof, is not anticipated by the reference disclosure (page 8, 4th full paragraph).

The Office contends that the amended claims read on one base pair as discussed above, and as such, Holt continues to anticipate the claimed invention.

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
April 13, 2005

A handwritten signature in black ink, appearing to read "Amy Nelson", with a long horizontal flourish extending to the right.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600